

REMARKS

Upon entry of the above amendment, claims 1, 3-7, 9-11, and 31-36 will be pending in the application, claims 2, 8, and 12-30 having been canceled and claims 34-36 having been added. Claims 1, 3-5, 9 and 10 have been amended. Support for the amendment can be found throughout the specification and in the claims as originally filed. For example, new claims 34-36 are supported by original claim 1 and by the specification at, for example, page 2, lines 3-18. No new matter is added by the amendment.

35 U.S.C. § 112, Paragraph 1 (Enablement)

The Examiner rejected claims 1-7, 11 and 31-33 for lack of enablement (Office action at pages 2-5). Before describing the grounds for rejection, the Examiner defines the subject matter that *is* considered enabled. More specifically, the Examiner states that:

the specification, *while being enabling for* an isolated polypeptide comprising the polypeptide of SEQ ID NO:1, wherein there is a mutation at the position corresponding to position 143 of SEQ ID NO:1, does not reasonably provide enablement for ... (Office action at page 2, emphasis added).

Consistent with this finding, the Examiner did *not* reject claim 8, which depended from claim 1 and specified that “the mutation comprises a mutation at the position corresponding to position 143 of SEQ ID NO:1”.

Applicants do not concede that the subject matter the Examiner initially found enabled is the only subject matter enabled by the present specification. However, to further prosecution, Applicants have amended claim 1, which is now directed to a mutant interleukin-7 (IL-7) polypeptide comprising an amino acid sequence having a mutation at position 143 of SEQ ID NO:1 or a non-human IL-7 polypeptide having a mutation at the position that corresponds to position 143 of SEQ ID NO:1.

In view of the foregoing, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph, for failure to satisfy the enablement requirement be withdrawn.

35 U.S.C. § 112, Paragraph 2

The Examiner rejected claims 1-11 and 31-33 as being indefinite. The Examiner states that the term “substantially pure” in claim 1 renders the claim indefinite because the term “is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree [of purity],... and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention” (Office action at page 5). Applicants respectfully disagree. The term “substantially pure” is defined in the specification. The Examiner’s attention is kindly directed to, for example, page 8 at lines 11-22.

The Examiner states that the recitation of “one or more amino acid...” in claims 1, 3, 4, and 5 renders the claims indefinite because it is unclear how many amino acid residues should be altered, if more than one. Applicants do not concede that this claim term is indefinite. However, the claims as amended to not recite “one or more amino acid...”

In view of the foregoing, Applicants request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

35 U.S.C. § 102

102(a). Claims 1, 2, 8-11 and 31 were rejected as being anticipated by vanderSpek *et al.* (*Cytokine* 17:227-233, 2002). The Examiner alleges that this reference meets all the limitations recited in the claims (Office Action at page 7).

Claims 2 and 8 have been canceled, so the rejection of these claims is now moot and should be withdrawn. With respect to claims 1, 9-11, and 31, the Examiner is asked to withdraw this ground for rejection because Applicants reduced the present invention to practice prior to the publication date of vanderSpek *et al.*, and vanderSpek *et al.* cannot, therefore, qualify as prior art. Filed herewith is a Declaration Under 37 C.F.R. § 1.131 by Dr. Francine Foss, who is a co-inventor of the subject matter now claimed as well as an author on vanderSpek *et al.* The very fact that Dr. Foss is an author on the vanderSpek *et al.* publication means that her contributions to the research published in that paper, including her work with the IL-7W143 mutants, must have been reduced to practice before the publication of vanderSpek *et al.* Otherwise, those

contributions could not have been described in the vanderSpek reference. Accordingly, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102(a) be withdrawn.

102(b). Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Gregoire *et al.* (a printout of a comparison (or alignment) of two sequences provided by the Examiner). The Examiner characterizes Gregoire as disclosing an IL-7 mutant that comprises several amino acid residues that are different than those found in the polypeptide of SEQ ID NO:1, at the carboxy terminus. The Examiner then concludes that the Gregoire reference meets all the limitations recited in pending claim 1 (Office action at page 7).

Applicants do not concede that Gregoire *et al.* is an anticipatory reference. However, claim 1 has been amended and is directed to a mutant interleukin-7 (IL-7) polypeptide comprising an amino acid sequence having a mutation at position 143 of SEQ ID NO:1 or a non-human IL-7 polypeptide having a mutation at the position that corresponds to position 143 of SEQ ID NO:1. The sequence aligned in Gregoire *et al.* does not include a mutation at position 143, as shown in the following partial reproduction of the alignment.

|     |            |                      |   |
|-----|------------|----------------------|---|
| 121 | VKGRKPAALG | EAQPTKSLEENKSLKEQKKL | ⌘ |
|     |            |                      |   |
| 121 | VKGRKPAALG | EPQPTKSLEENKSLKEQKKL | ⌘ |

As there is no mutation at position 143, Gregoire *et al.* cannot anticipate the present claims. Applicants request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

### 35 U.S.C. § 103

Claims 1, 32 and 33 were rejected under 35 USC § 103(a) as being unpatentable over vanderSpek *et al.* in view of Capon *et al.* (U.S. Patent No. 5,116,964).

For the reason provided above, vanderSpek *et al.* does not qualify as 102(a) prior art and thus does not anticipate the pending claims. Therefore, vanderSpek *et al.* is also not available as prior art under 35 U.S.C. § 103 (see MPEP 2141.01). Capon *et al.* alone, which broadly discloses fusion proteins that include an immunoglobulin polypeptide fused to a ligand binding partner, is not sufficient to render the present claims obvious. For obviousness, the prior art must

teach or suggest all the limitations of the subject matter claimed, and Capon does not teach or suggest Applicants' mutant IL-7 polypeptide. Applicants therefore respectfully request that the rejection of claims 1, 32, and 33 under 35 USC § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing, Applicants contend that the present claims are now in condition for allowance, which action is respectfully requested. *Should the Examiner maintain any of the present grounds for rejection, the favor of a telephone call to the undersigned is respectfully requested.*

Enclosed is a \$510 check for the Petition for Extension of Time for three months. Please apply any other necessary charges or any credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 00398-152001.

Respectfully submitted,

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